OCT 1 6 2001

K011530

510(k) Summary

Submitted on behalf of:

	Company Name:	**FENA Designs, Inc.**
	Address:	1914 Division Street W, Ste 9106 St. Cloud, MN 56301
	Telephone:	**320-259-7844**
	Fax:	**320-3979031**
by:	Paladin Medical, Inc. PO Box 560 Stillwater, MN 55082	
Telephone:	715-549-6035	
Fax:	715-549-5380	

CONTACT PERSON: **Elaine Duncan**
DATE PREPARED: **May 12, 2001**
TRADE NAME: **VERTRAN standing wheelchair**
COMMON NAME: **Wheelchair-Powered Standup (standing)**
SUBSTANTIALLY EQUIVALENT TO: LEVO LCM

DESCRIPTION of the DEVICE: The VERTRAN standing wheelchair is a powered chair. The VERTRAN wheelchair is propelled and steered by varying the speed of the two front wheels using two independent gear motors. Rear casters support the rear of the chair and allow the chair to pivot when the drive wheels move. The system is controlled with a standard wheelchair controller, with direct user operation through a standard wheelchair joystick. Two deep cycle 12-volt batteries, connected in series, supply the energy for the system. A linear actuator drives and rotates the seat to a vertical position. The linear actuator is connected to the base at one end and to the seat at the other end. The back pivots with respect to the seat by means of a four-bar linkage structure.

The VERTRAN standing wheelchair is built to provide balance and stability in both the seated and standing positions and designed to be mobile in the standing position. Users are cautioned to read and understand all safety instructions prior to using the chair and to avoid unsafe conditions that could make the chair unstable. The VERTRAN standing wheelchair is designed to be adjusted by an authorized service technician to each user's needs and preferences. The various adjustments include: speed and dampening performance, acceleration rates and turning speeds, and seat height and depth for comfort and fit. The VERTRAN standing wheelchair features, such as a removable knee brace, arm rests that flip out of the way, and central lift mechanism design, make transfers in and out of the chair easier.

INDICATIONS FOR USE: The VERTRAN standing power wheelchair offers seated and standing mobility to users with ambulatory impairments.

SUMMARY of TESTING:

STANDARD(S)
ANSI/RESNA(ISO 7176 equivalent) WC-93, 01;02,03,04,05,06,07,08,09,10,14:parts 6, 7, 8, 9,10 and 20.
Repeat of Part ANSI/RESNA Part 20; 19.1 for revised knee brace.
Immunity Requirement of ANSI/RESNA Vol 2: Section 21 Electromagnetic Compatibility
EN 61000-3-2: Electromagnetic Compatibility Limits for Harmonic Current Emissions, also EN 61000-3-3: Electromagnetic Compatibility.
EN 60601-1-2: Part 1- Section 1.2-Electromagnetic Compatibility-Requirements & Tests ; ANSI/RESNA WC/Vol2: Section 21 and also FCC Part 15 and EN 55011 Limits and Methods of Measurement of Radio Interference

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 6 2001

FENA Design, Inc.
c/o Ms. Elaine Duncan, M.S.M.E., RAC
President
Paladin Medical, Inc.
P.O. Box 560
Stillwater, Minnesota 55082

Re: K011530
Trade/Device Name: Vertran Standing Wheelchair
Regulation Number: 890.3900
Regulation Name: Standup wheelchair
Regulatory Class: II
Product Code: IPL
Dated: September 7, 2001
Received: September 10, 2001

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K011530

Device Name: VERTRAN Standing Wheelchair

Indications for Use:

The VERTRAN standing power wheelchair offers seated and standing mobility to users with ambulatory impairments.

(Please Do Not Write Below This Line-Continue On Another Page If Needed)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over -The-Counter Use _____

(Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011530